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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,111	02/15/2002	C. Gordon Todderud	D0031 NP	1564

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EXAMINER

ZARA, JANE J

[REDACTED]  
ART UNIT 1635 PAPER NUMBER

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/077,111

Applicant(s)

TODDERUD ET AL.

Examiner

Jane Zara

Art Unit

1635

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply****A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 03 October 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 5,6,9-14,21-28 and 32-40 is/are pending in the application.  
4a) Of the above claim(s) 5,6,9-14,18 and 19 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 21-28 and 32-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10-17-05.

- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: ACB report.

## **DETAILED ACTION**

This Office action is in response to the communication filed 10-3-05.

Claims 5, 6, 9-14, 18, 19, 21-28, 32-40 are pending in the instant application.

### ***Election/Restrictions***

This application contains claims 5, 6, 9-14, 18, 19, drawn to an invention nonelected with traverse in the election filed 6-9-04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Any rejections not repeated in this Office action are hereby withdrawn.

#### **Maintained Rejections**

Claims 21, 26, 28, 32-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record set forth in the Office action mailed and for the reasons set forth below.

The claims are drawn to isolated polynucleotides and methods comprising a nucleotide sequence at least 97% identical to SEQ ID NO: 12, or encoding an amino acid sequence of a cell signaling polypeptide involved in cell signaling cascade and having at least 97% sequence identity with SEQ ID NO: 13, or a polynucleotide having

Art Unit: 1635

the nucleic acid sequence of ATCC Accession No. PTA-3161, or an isolated polynucleotide encoding a human RET16.2 polypeptide, or detecting a polynucleotide encoding a ubiquitin conjugating enzyme or fragment thereof that hybridizes to the polynucleotides described directly above. The specification and claims do not adequately describe the elements essential to the genera comprising these sequence variants, nor do they describe the genus comprising a cell signaling polypeptide involved in a cell signaling cascade or ubiquitin conjugating enzyme or fragment thereof having at least 97% identity with SEQ ID NO: 12 or 13. The disclosure does not clarify the common attributes encompassed by these very broad genera.

The scope of the claims includes numerous structural variants and the genera are highly variant because a significant number of structural differences between members of a given genus is permitted. Concise structural features that distinguish structures within the various genera are missing from the disclosure and the claims. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the various genera claimed. Thus, Applicant was not in possession of the claimed genera.

Applicant's arguments filed 10-3-05 have been fully considered but they are not persuasive. Applicant argues that adequate written description has been provided for the claimed invention because the genera claimed have been limited to specifically defined species within the specification. Applicant argues further that one skilled in the art would be able to easily identify the specific species now claimed by reviewing the sequences identified in the examples of the instant disclosure and that the claimed

sequences are involved in a cell signaling cascade, and further that one skilled in the art would know that the U box domain containing proteins mediate ubiquitination. Contrary to Applicant's assertions, the genera presently claimed - encompassing any polynucleotide sequence sharing at least 97% identity with SEQ ID NO: 12, or any polynucleotide sharing at least 97% sequence identity with a polynucleotide encoding the amino acid sequence of SEQ ID NO: 13, or a polynucleotide having the nucleic acid sequence of ATCC Accession No. PTA-3161, or an isolated polynucleotide encoding a human RET16.2 polypeptide, or a method of detecting a polynucleotide encoding a ubiquitin conjugating enzyme or a fragment thereof that hybridizes to the polynucleotides described directly above - comprise a myriad of sequences and the instant disclosure does not adequately describe a representative number of species that perform the function claimed, of encoding cell signaling polypeptides involved in cell signaling cascades. A representative number of species of polypeptides with the function claimed must be adequately described and must fairly represent the variation encompassed within the entire genera. The specification describes various WD, SAM and U-box domains within the polypeptide claimed, as well as splice variations which lack some of these common domains or motifs. The presence of these common motifs, however, does not address the question of what structures are required for defining members of the broad genera claimed from those outside of the claimed genera (see e.g. Accession Nos. BC029520 ; see also Collins, F.S., Proc. Natl. Acad. Sci., Vol. 99, No. 26, pages 16899-16,903, Dec. 2002) for a disclosure other polypeptides embraced by the broadly claimed genera, but not attributed the functionality claimed). Because

the prior art is silent with respect to what structures are precisely required beyond the presence of well known domains, disclosure of a polypeptide comprising the common motifs of WD, SAM and U-box domains does not sufficient to fulfill the written description requirement of the broad genera claimed. One of skill in the art would conclude that Applicant was not in possession of the broadly claimed genera.

Rejections Necessitated by Amendments

**Claim Rejections - 35 USC § 102/103**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Birren et al.

Birren et al (Direct Submission of Accession No. AC006501, submitted 2-26-99) teach a method of detecting a polynucleotide encoding a fragment of a cell signaling

cascade protein having at least 97% identity with SEQ ID NO: 12 or 13 (see the accompanying sequence alignment data, clone obtained from genomic DNA from "RPCI-11 human BAC library"). The burden of establishing whether the prior art polynucleotide has the function of encoding a fragment of a cell signaling cascade protein as claimed falls to applicant. See (In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977): "Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product... Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced b the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted]. See also MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing In re Fitzgerald 205 USPQ 594, 596 (CCPA 1980), quoting In re Best 195 USPQ 430 as per above. Therefore, absent evidence to the contrary, since the polynucleotide disclosed by Birren et al meets all of the structural limitations of the instantly claimed invention, it would necessarily be presumed to have the functionality claimed, of encoding a fragment of a cell signaling cascade protein encoded by the polynucleotide of SEQ ID NO. 12.

Therefore, absent evidence to the contrary, claim 36 is anticipated by or, in the alternative, obvious over Birren et al.

New Rejections

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-36, 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-36 and 38-40 recite are drawn to compositions comprising a single polynucleotide, but they depend from claims that are drawn to several polynucleotides. The metes and bounds of claims 32-36 and 38-40 therefore cannot be determined. Appropriate clarification is required.

**Allowable Subject Matter**

SEQ ID No. 12 appears free of the prior art searched and of record.

**Conclusion**

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

Art Unit: 1635

(December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone number for the Group is **571-273-8300**. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(571) 272-0765**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (571) 272-0564. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**Jane Zara  
12-14-05**

*Jane Zara  
TC1600*